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COMMENTARY

International Society for Medical Publication Professionals (ISMPP) position statement: the role of the professional medical writer

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ABSTRACT

The International Society for Medical Publication Professionals (ISMPP) is an independent, nonprofit professional association with members from the pharmaceutical, medical device, and biotechnology industries; publication planning and medical communications companies; academia; and medical journal staffs, including editors and publishers. ISMPP's mission is to support the educational needs of medical publication professionals by providing a forum to facilitate awareness and development of best practices in publication planning and implementation, and fostering consensus policies related to medical publishing.

This position statement reflects our concern about the current climate of mistrust regarding the use of professional medical writers in the preparation of manuscripts. We acknowledge the skills and training of medical writing professionals and support their role in working with research teams to develop clear and concise manuscripts in a timely fashion. Further, we support complete and transparent disclosure of the role of the medical writer and the source of funding for the writing initiative in order to build awareness of, and trust in, the appropriate use of medical writing professionals. ISMPP endorses use of the contributorship model, which offers detailed information on the roles of all who participated in planning, conducting, developing, and publishing medical research. Further, we propose that this model be integrated into the standard operating procedures of the diverse organizations that comprise our membership because the responsibility for authorship disclosure is shared by sponsors, authors, study investigators, and medical writers. Finally, we commend the many organizations that have worked to increase recognition and understanding of the legitimate role of the medical writer, and are eager to work in concert with them to ensure the rigorous maintenance of all ethical standards for reporting the results of medical research.

Introduction

Scientific discovery and publication of research findings are cornerstones of the scientific method. Research relies on the coordinated effort of scientists, physicians, statisticians, project managers, regulatory advisors, and others. It traditionally has been assumed that those who directed the research would communicate the scientific findings. However, researchers do not always have the time or inclination to write, and drafting manuscripts may not be their highest priority or strength.

The International Society for Medical Publication Professionals (ISMPP) believes that medical writers can often improve the efficiency and effectiveness of manuscript preparation by working with the research team to develop clear and concise manuscripts in a timely fashion. Unfortunately, the role of the medical writer has been poorly understood by some and disparaged by others. ISMPP is concerned about the current climate of mistrust and hopes to correct some misperceptions by defining the legitimate role of the medical writer and by affirming our support for complete and transparent disclosure of all those who contribute to publishing research findings.

The professional medical writer

Medical writers have diverse backgrounds and varied associations with the pharmaceutical industry or academic institutions. Writers may be employees of pharmaceutical companies or medical communications agencies or they may work on a freelance basis or as consultants. Many have advanced degrees in the life sciences or are themselves physicians.

Regardless of background, the medical writer's role is to produce manuscripts based on (1) scientific or clinical data and (2) a thorough literature search to identify and assess relevant publications on the topic. Ideally, such writers collaborate with the designated authors at the beginning of the writing process and throughout the development of the manuscript. Writers may also prepare figures and tables, track author feedback, and perform other time-consuming tasks to enhance the quality of the manuscript and reduce delays, thus freeing the researchers to focus on their primary task, which is to assume responsibility for the publication's overall content, tone, and accuracy.

In addition to their communication skills, medical writers generally are more familiar than investigators or sponsors with writing and publication guidelines, which are designed to ensure that articles are written according to generally accepted standards. These standards also address the more technical aspects of preparing and submitting manuscripts to facilitate review by journal editors and peer reviewers. Many useful standards have been published, including:

- Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication (also known as the International Committee of Medical Journal Editors [ICMJE] guidelines or Vancouver guidelines)[1], which have been endorsed by more than 600 biomedical journals
- Principles for conduct of clinical trials and communication of clinical trial results from the Pharmaceutical Research and Manufacturers of America (PhRMA)[2], which was prepared by members of the research-based pharmaceutical and biotechnology companies to set forth principles on the ethical conduct of clinical trials and appropriate disclosure of clinical trial results
- Good publication practice (GPP) for pharmaceutical companies[3], which was prepared by a group of pharmaceutical industry employees "to ensure that clinical trials sponsored by pharmaceutical companies are published in a responsible and ethical manner"
- The American Medical Writers Association (AMWA) position statement on the contribution of the biomedical communicator[4], published in 2003 to augment AMWA's policy on ethical standards for biomedical communicators, which dates back to 1940
- The European Medical Writers Association (EMWA) guidelines on the role of medical writers in developing peer-reviewed publications[5], which offers guidance specifically for medical writers who prepare publications on behalf of authors to ensure that their reports are accurate and scientifically valid
- The Consolidated Standards of Reporting Trials (CONSORT) statement for reporting the results of randomized controlled trials[6], which has been endorsed by the ICMJE, The Council of Science Editors (CSE), and The World Association of Medical Editors (WAME)

Medical writers also should be familiar with and adhere to individual journal requirements, which provide direction on the details of content, such as style (e.g., structured or unstructured abstract), format, word count, and disclosure guidelines. Disclosure focuses on authorship criteria, financial information, and potential conflicts of interest as they relate to authors, contributors, and sponsors. A consensus among these guidelines and most publication standards is that full and transparent disclosure is required of all contributors, including medical writers. When a journal lacks such guidance, the medical writer should address

the importance of transparency and provide an explicit description of the relationship of all contributors to the sponsor, along with full disclosure of funding sources for the research and the writing initiative. Publication of this information takes place at the discretion of the journal.

Varying standards

Currently, there is no universal standard on how to disclose the role of the medical writer. ICMJE guidelines state that:

All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chair who provided only general support. Editors should ask authors to disclose whether they had writing assistance and to identify the entity that paid for this assistance[1].

To be named as an author, according to ICMJE guidelines, an individual must meet all three of the following criteria: (1) make "substantial contributions to [the] conception and design, or acquisition of data, or analysis and interpretation of data"; (2) draft or revise the article for important intellectual content; and (3) approve the final version for publication. Further, "All persons designated as authors should qualify for authorship, and all those who qualify should be listed"[1].

Generally, medical writers do not meet ICMJE authorship criteria as they relate to reporting the results of original research and, as such, should not be designated as authors. However, when medical writers do contribute substantially to designing a study protocol, planning the data analysis or interpreting study results, and when they are asked to approve the final manuscript version, the writer does meet ICMJE authorship criteria and merits authorship. Medical writers also may make substantial contributions to other types of research, such as systematic or clinical reviews. EMWA states that medical writers may qualify for authorship in some circumstances, for instance, if they conduct an extensive literature search for a review article[5]. In such cases, the writer, along with the other named authors, takes public responsibility for the research.

Although ICMJE criteria for authorship have been adopted by many biomedical journals, they are by no means universally accepted[7]. Disputes over authorship are among the most common in medical research, including academic institutions where they have been described as "…memorable and upsetting"[8]. Authorship issues may be viewed in two broad categories. The first is misattribution of credit (for work done prior to publication) and includes basic decisions about byline authors – how many, in what order – as well as questions about gift, ghost, and guest authorship. The second is failure to take responsibility for the work (i.e., as a guarantor) – particularly when challenged following publication. Partly in response to these concerns, the use of contributorship has recently been adopted by some medical journals, and offers a way to clearly identify the role of the various participants in a research project, including a professional medical writer.

Contributorship

Contributorship identifies all those who participated in the work, whether or not they qualify for authorship. Some journals, such as the British Medical Journal (BMJ), have moved from authorship to contributorship because they believe that the ICMJE definition of authorship "does not make clear who has contributed what to the published study"[9]. BMJ publishes authors' names at the beginning of a paper and then provides a specific listing of contributors at the end of the paper (some of whom may not have been named authors), along with details on each person's individual contribution (such as obtaining funding for the research, planning a trial or conceiving the idea for a review, performing statistical analysis, or writing the article).

BMJ requires all contributors to state their affiliations and specify whether they received any compensation related to the research or the manuscript preparation. Because each author may not be equally familiar with all aspects of the work, BMJ asks that one or more contributors be designated as guarantors of the paper, which means they accept full responsibility for the manuscript[9].

The trend toward contributorship is relatively new and is evolving. However, WAME encourages this practice in their current policy statement[10]. At this time, ISMPP strongly endorses the concept of contributorship because it provides the most explicit description of the actual work of all persons responsible for conducting and reporting on the scientific research.

To facilitate the contributorship model, ISMPP recommends compiling the following information for everyone who has assisted in researching, developing, and publishing a scientific paper:

- Full name and highest professional degree.
- Affiliation/employer.
- Specific role in the planning/conduct/analysis of the trial and in preparation of the manuscript.
- Any compensation or consideration received and its source.

ISMPP suggests including a contributor list with the cover letter upon submitting a manuscript to a journal. The journal then can decide whether to publish this information. Because the contributorship model is not yet widely recognized, the manuscript submission should also comply with each individual journal's requirements as they relate to authorship.

Opportunities

ISMPP endorses the use of the contributorship model and proposes that it be integrated into the standard operating procedures of the diverse organizations that comprise its membership. Further, ISMPP intends to convene a consensus summit on this and related topics and to work with others in industry, academia, medical communications, and the biomedical press to adopt the new standard more broadly.

We commend other organizations that have worked to increase recognition and understanding of the important role of the medical writer, and we are eager to move forward in concert with them to ensure the rigorous maintenance of all ethical standards for reporting the results of medical research.

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